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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,876	06/01/2001	Jean-Rene Authelin	FI5028-US-CNT	2065

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/871,876	AUTHELIN ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination and Information Disclosure Statement filed on January 21, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jinks (US 4810488). Jinks teaches a crystalline material with a reduced particle size of 2 to 5 microns (Col. 6, Claims 6-10). The material is an anti-inflammatory steroid (Col. 6, Claims 6-10; Col. 1, lines 10-24). This teaching anticipated Claims 12 and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jinks. The teachings of Jinks are discussed above. Jinks does not teach the exact particle sizes to have a median particle size of 1 or 2 microns. Jinks does teach the particle range to be below 10 microns and preferably 2 to 5 microns.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the particle size of the steroid to achieve a mean particle size of 1 or 2 microns. The active agent in micronized using a fluid energy mill (Col. 3, Examples 1 and 2).

One of ordinary skill in the art would have been motivated to do this prepare an active agent to be implemented in an aerosol formulation for inhalation into the human bronchial system.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weishaupt et al. (US 3897010) in view of Hagen et al. (US 4767612) alone, or further in view of Capelle, Jr. et al. (US 6145765).

The Weishaupt reference teaches a method of milling material wherein a fluid energy mill is employed to micronized the material wherein the fluid is an inert gas at low temperature (Col. 2, lines 50-65; Col. 4, lines 19-34). The temperature of the fluid lies in a cryogenic range or a range of the liquefaction temperatures of the inert gas used in the method (Col. 4, lines 19-34). The purpose of the low temperature is to bring

the milling material to a low temperature to embrittle the material to facilitate pulverization in the fluid energy mill (Col. 2, line 66 – Col. 3, line 17). The temperature of the fluid is reduced to a point such that the material to be milled is no longer plastically or elastically viscous but ruptures readily upon impact with a surface or another particle (Col. 2, line 66 – Col. 3, line 17).

Weishaupt does not expressly teach that the material to be milled is triamcinolone acetonide. The reference further does not expressly teach the inert gas to be helium but rather implicitly teaches the gas to an inert gas, which encompasses helium gas.

The Hagen reference teaches the micronization of triamcinolone acetonide in a fluid energy mill. The particle size range of the micronized triamcinolone acetonide is from 1 to 5 microns (Col. 2, lines 55-59).

While the reference does not teach the complete temperature range, differences in temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to mill triamcinolone acetonide in a fluid energy mill at low temperatures to a mean particle size of 2 microns.

One of ordinary skill in the art would have been motivated to do this to provide a method that embrittles the milled material to be comminuted, which results in a substantial increase in the throughput of the apparatus for a given energy and in turn provides a substantial increase in efficiency.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Further, the Capelle, Jr. reference teaches that the inert gas used as the fluid for a fluid energy mill can be helium (Col. 5, lines 20-31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate helium as the fluid in the fluid energy mill.

One of ordinary skill in the art would have been motivated to do this to choose a gas that is compatible with the material being processed and does not degrade the material upon contact with the fluid (Capelle, Jr., Col. 5, lines 20-31).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed January 21, 2004 have been fully considered but they are not persuasive.

Applicant first argues that Claim 12 and 13 are novel and non-obvious because the prior art cited is silent as to the amorphous content of the crystals produced in the reference. In response, the Examiner would like to first point out that the prior art is silent as to the amorphous content which can be interpreted to mean that no amorphous

content is found in/on the crystals. Second, applicant had not shown that the prior art, which is silent as to amorphous content, has an amorphous content greater that 5%. Therefore, applicant's arguments to the contrary are unpersuasive.

Applicant further argues that the combination of references cited for the remainder of the claims does not render obvious the instant invention. Applicant argues that the prior art teaches the temperature range of the gas is in the cryogenic range, which is defined in the prior art. It is the ***range*** of temperatures at which inert gases liquefy but generally teaches below –100 degrees Celcius. Therefore, part of the range overlaps with the instant claimed range of –30 degrees to –120 degrees Celcius. Further applicant argues that the gas to be used for the milling is in liquid form. Upon careful review of the prior art, the gas is not in liquid form when used in the energy mill to comminute particles (See Col. 4, lines 19-34; Col. 5, lines 5-21; Col. 6, lines 42-58; Col. 7, lines 8-28). Therefore, applicant's argument that the prior art teaches away from using gas, as opposed to liquefied gas, is unpersuasive.

Further, the rejection of Claim 1-22 based on Weishaupt, Hagen and Capelle is maintained. The primary reference does not disclose the exact particle size but is again teachings the method of the instant claims. A fluid energy mill is used in the presence of low temperature inert gases to prepare comminuted or pulverized particles. Hagen teaches that triamcinolone acetonide can be micronized using a fluid energy mill to a particle size of 1 to 5 microns. Capelle teaches that a known inert gas for fluid energy mills is helium. At the time the invention was made it would have been obvious to use a fluid energy mill to produce micronized particles of triamcinolone acetonide in a helium

environment at low temperatures. The limitations applicants rely on for their arguments are not recited in the independent claims; therefore, the Examiner fails to see the criticality in such limitations when the prior art teaches the method of the instant claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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